



MANAGEMENT SYSTEMS ACCREDITATION PROGRAM (MSAP)

Scope of Accreditation

Accredited Legal Entity: Laboratoire National de métrologie et d'Essais (LNE)
G- MED Certification Division Trading as LNE/G-MED

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Regulatory Affairs

LOCATION A

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SCC File Number:	08030
Accreditation Standards:	ISO/IEC 17021:2011 IAF MD1, MD2, MD5
Initial Accreditation Date:	2004-07-27
Reaccreditation Date:	2016-03-17
Accreditation Expiry Date:	2020-07-27

Additional Critical/Key Locations:

Location	Country	Address	City
B	France	19 D rue de la Télématique 42000 Saint-Étienne France	Saint-Étienne
C	United States	3930 Knowles Ave. Suite 306 Kensington, Maryland 20895	Maryland



I: Medical Devices Quality Management Systems Program

Base program:	Medical Devices Quality Management Systems	
Additional accreditation standards	GD207; GD210; GD211; Q90R0 IAF MD9	
Certification standards:	ISO 13485:2003 under CMDCAS ISO 13485:2016 under CMDCAS ISO 13485:2003 ISO 13485:2016	
Locations:	A-C	
Certification Body's main technical areas: (IAF MD 8 & MD 9)	Non-active Medical Devices	<ul style="list-style-type: none"> • General non-active, non-implantable medical devices • Non-active implants • Devices for wound care • Non-active dental devices and accessories • Non-active medical devices other than specified above
	Active Medical Devices (Non-Implantable)	<ul style="list-style-type: none"> • General active medical devices • Devices for imaging • Monitoring devices • Devices for radiation therapy and thermo therapy • Active (non-implantable) medical devices other than specified above
	Active Implantable Medical Devices	<ul style="list-style-type: none"> • General active implantable medical devices • implantable medical devices other than specified above
	In Vitro Diagnostic Medical Devices (IVD)	<ul style="list-style-type: none"> • Reagents and reagent products, calibrators and control materials for: <ul style="list-style-type: none"> – Clinical Chemistry – Immunochemistry (Immunology) – Haematology/Haemostasis/Immunoematology – Microbiology – Infectious Immunology – Histology/Cytology – Genetic Testing • In Vitro Diagnostic Instruments and software • IVD medical devices other than specified above
	Sterilization Method for Medical Devices	<ul style="list-style-type: none"> • Ethylene oxide gas sterilization (EOG) • Moist heat • Aseptic processing • Radiation sterilization (e.g. gamma, x-ray, electron beam)



		<ul style="list-style-type: none">• Sterilization method other than specified above
	Devices incorporating/utilizing specific substances/technologies	<ul style="list-style-type: none">• Medical devices incorporating medicinal substances• Medical devices utilizing tissues of animal origin• Medical devices utilizing micromechanics• Medical devices utilizing nanomaterials• Medical devices utilizing biological active coatings and/or materials or being wholly or mainly absorbed• Medical devices incorporating or utilizing specific substances/technologies/ elements, other than specified above

This document forms part of the Certificate of Accreditation issued by the Standards Council of Canada (SCC) to Laboratoire National de métrologie et d'Essais (LNE) G- MED Certification Division Trading as LNE/G-MED The original version is available in the Directory of Accredited Management Systems Certification Bodies on the SCC website at www.scc.ca.

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Vice President, Accreditation Services
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